UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,567	06/19/2006	Jean-Marie Beau	P/3610-67	8886

2352 7590 11/04/2008

OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK, NY 100368403

EXAMINER	
GOON, SCARLETT Y	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
11/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,567	BEAU ET AL.	
	Examiner	Art Unit	
	SCARLETT GOON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *13-18,29-33,37,38 and 48-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,19-28,34-36 and 39-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *19 June 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-52 are pending in the instant application.

Priority

This application is a National Stage entry of PCT/EP04/14909 filed on 22 December 2004 and claims priority to France foreign application 0315543 filed on 30 December 2003. A certified copy of the foreign priority document in French has been received. No English translation has been received.

Information Disclosure Statement

The information disclosure statement filed 19 June 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-47, drawn to a compound of formula (I) wherein B is an arylene or naphthylene, in the reply filed on 18 September 2008, is acknowledged. The traversal is on the ground(s) that the invention includes a generic formula and the examination of the generic formula would encompass all

species. This is not found persuasive because of the requirement for restriction under Markush practice.

(f) "Markush practice" The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The different variables A, B, C, D, n, R^1, R^2, R^3, R^4, R^5, R^6, R^7, R^8 and R^9 result in compounds that

have achieved a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus.

Furthermore, as indicated on p. 3 of the Office Action dated 18 July 2008, the common specially technical feature in all groups is the base trisaccharide structure of formula (I) wherein n=1. As this compound was indicated to have been taught by Robina *et al.* (of record), this element cannot be a special technical feature under PCT Rule 13.2. Thus, lack of unity is apparent and the requirement for restriction is deemed proper.

The Applicants further elect Compound (3) as the species for the compound of formula (I), with traverse, in the reply filed on 18 September 2008. The traversal is on the ground(s) that the invention includes a generic formula and the examination of the generic formula would encompass all species. This argument is not found persuasive as discussed above.

The requirement is still deemed proper and is therefore made FINAL.

Claims 48-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 13-18, 29-33, 37 and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 1-12, 19-28, 34-36 and 39-47 will be examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 19-28, 34-36 and 39-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some compounds of formula (I), does not reasonably provide enablement for all compounds of formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

All of the *Wands* factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The rejected invention is drawn to a compound of formula (I) in which all variables are indicated within the claim.

Relative skill of those in the art: The relative skill of those in the art is high.

Breadth of claims: The claims are extremely broad in that they encompass a large number of possible structural components for each variable of the compound of formula (I).

State of the prior art/Predictability or unpredictability of the art: The skilled artisan would view that the synthesis of all possible variations of the compounds of formula (I) would require much experimentation. Expand this part such as give some examples of a synthesis of one compound of formula (I) would be unpredictable chemically. Explain why this would be unpredictable and if you know any paper talking about this. You should cite a paper to support your position.

Amount of guidance/Existence of working examples: More importantly, there are working examples present for only a subset of the possible variations of compounds of formula (I). Working examples are only present for the compound of formula (I) wherein n is 2 or 3, A is -C(O)- or $-CH_2-$, B is a phenylene, C is –O-, D is a linear, saturated or unsaturated hydrocarbon-based chain containing 11 carbon atoms in length, E and G is NHAc, R^1 is $C(O)CH_3$, R^2, R^3, R^4, R^5, R^6, R^7, and R^9 are all H, and R^8 is SO_3Na or fucose (p. 46-66 of instant specification). No working examples are present for any other substituents of the variables claimed in instant claim 1.

Lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164. I'm not sure this can apply here unless the synthesis of this type of compounds is undeveloped art.

Thus, the specification fails to provide clear and convincing evidence in sufficient support for making the claimed compounds as recited in the instant claims.

Genetech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors as discussed above, e.g., the amount of guidance provided and the lack of working examples, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-12, 19-28, 34-36 and 39-47 are rejected under 35 U.S.C. 102(a) as being anticipated by journal publication by Grenouillat *et al.* (PTO-892, Ref. U).

Grenouillat *et al.* disclose nodulation-factor analogues that exhibit high affinity towards a specific binding protein. The analogues, compounds 12-16, are shown in Scheme 4 (p. 4645, column 2).

Compound 12, disclosed by Grenouillat *et al.*, anticipates claims 1-12, 19-28, 34-36 and 39-47.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SCARLETT GOON/

Examiner
Art Unit 1623